

DETAILED ACTION

1. The Preliminary amendment filed 26 May 2006 is acknowledged and entered.

Informal Matters

2. The correct Application Number (i.e., USSN) for the instant Non-Provisional Application currently under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/580,851. To properly correlate all papers related to the instant application, please ensure to quote said USSN (i.e., 10/580,851) in all future correspondence with this Office.
3. The instant application (i.e., 10/580,851) has been assigned to Art Unit 1657 at the USPTO. To aid in correlating any papers for the instant application (i.e., 10/580,851), all further correspondence regarding the instant application (i.e., (i.e., 10/580,851)) should be directed to Art Unit 1657.
4. The assigned Examiner to the above-cited application (i.e., (i.e., 10/580,851)) at the USPTO is Kailash C. Srivastava. To aid in correlating any papers for the instant application, all further correspondence regarding the instant application (i.e., (i.e., 10/580,851)) should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

5. Claims 1-20 are currently cancelled.

Election /Restriction

6. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1 and 37 C.F.R. §1.475. Restriction to one of the following inventions is required under 35 U.S.C. §121 and §372.

In accordance with rules cited *supra*, applicant(s) is/are required, in reply to this Office Action, to select a single invention to which the claims must be restricted.

- Group I, consisting of claims 1-10 drawn to a method to qualitative, or semi-quantitative determination of endogenous amino acids L-phenylalanine, L-tyrosine, L- 3,4-dihydroxyphenylalanine and their corresponding keto-acids in biological fluids to diagnose and monitor metabolic disorders of said amino acids;

- Group II, consisting of claims 11-20, drawn to a kit (i.e., reagent composition) to diagnose and monitor said metabolic of said amino acids.

Inventions are Independent and Distinct

7. The inventions listed in Groups I-II above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The patent rules under 37 C.F.R. §1.475 for Unity of Invention (Paragraphs (a), (b) and (c)) are cited below:

§1.475 Unity of Invention before the International Searching Authority, the International Preliminary Examining Authority and during the National Stage

(a) An International and National Stage Application shall relate to one invention only, or to a group of inventions so linked as to form a general inventive concept (“requirement of unity of invention”). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as whole, makes over the prior art.

(b) An International or a National stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

Inventions described in Groups I-II *supra* fall within category (2), a product and a method of use of said product.

8. PCT Rule 13.2 does not provide for multiple compositions, or multiple methods of making a composition, or multiple methods of use of a composition within a single application. Thus, the first

appearing composition is combined with a corresponding first method of making said composition (if applicable) and/ or use of said composition. However, the additional composition and method claims each constitute a separate inventive Group.

In addition to the requirement that a Group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, e.g., as a composition and a method of use of said composition, must have a special technical feature that unites them. See Patent rules under 37 C.F.R. §1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

The special technical feature of the group method to qualitatively or semi-quantitatively determine said amino acid is well known in the relevant art (see, e.g., Dooley, 1992. Enzymatic Methods for Phenylketouria Screening Using Phenylalanine Dehydrogenase. Clinical Biochemistry, Volume 25, Number 4, Pages 271-275, especially Page 272, Column 2, Line 1 below Table 1 to Page 283, Column 1, Line 27, below Figure 3; Figure 3; Figure 5).

The special technical feature of Group II composition that of a kit (i.e., reagent) is also well known in the relevant art (see, e.g., Dooley, 1992. Enzymatic Methods for Phenylketouria Screening Using Phenylalanine Dehydrogenase. Clinical Biochemistry, Volume 25, Number 4, Pages 271-275, especially, Page 271, Column 2, Line 47 to Page 272, Column 1, Line 22 below Figure 1).

Thus, the claimed composition and method lack unity of invention because the alleged special technical feature is not a contribution over the art.

9. In accordance with 37 C.F.R. §1.499, applicant (S) is/are required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant(s) is/are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 C.F.R. §1.143).

10. Applicant (s) is/are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, § 102, § 103, and § 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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30 March 2010

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